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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/648,464  | 08/25/2003  | James D. Ralph       | F-286                        | 8288             |
| 51640   | 7590        | 02/28/2006           |                              |                  |
| SPINE MP<br>LERNER, DAVID, et al.<br>600 SOUTH AVENUE WEST<br>WESTFIELD, NJ 07090 |             |                      | EXAMINER<br>BLANCO, JAVIER G |                  |
|   |             |                      | ART UNIT                     | PAPER NUMBER     |
|   |             |                      | 3738                         |                  |

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/648,464             | RALPH ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Javier G. Blanco       | 3738                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-16, 18, 20, 21 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-16, 18, 20, 21, and 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Previous Office Action***

1. As indicated during the telephonic interview of January 26, 2006, the finality of the previous Office Action, mailed on July 28, 2005, is hereby withdrawn.

### ***Response to Amendment***

2. Applicants' amendment of claims 13, 15, 16, 18, 20, 21, 23, and 24 in the reply filed on January 30, 2006 is acknowledged.
3. Applicants' cancellation of claims 17, 19, and 22 in the reply filed on January 30, 2006 is acknowledged.

### ***Terminal Disclaimer***

4. The terminal disclaimer filed on January 30, 2006 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of Application No. 10/140,153 and US 6,863,689 has been reviewed and is NOT accepted. The assignee has not established its ownership interest in the application, in order to support the terminal disclaimer. There is no submission in the record establishing the ownership interest by either (a) providing documentary evidence of a chain of title from the original inventor(s) to the assignee, or (b) specifying (by reel and frame number) where such documentary evidence is recorded in the Office (37 CFR 3.73(b)).
5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 13-15, 21, and 24-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 8-10 of copending Application No. 10/140,153. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim an intervertebral spacer device comprising a deflectable wire mesh secured over, and spaced apart from, the exterior surfaces of the first and second plates.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 13-15, 21, and 24-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No.

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6,863,689. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 13-15, 21, and 24-26 of this application and claims 1-3 of US 6,863,689 lies in the fact that the patent claims include many more elements and is thus much more specific. Thus the invention of claims 1-3 of US 6,863,689 is in effect a “species” of the “generic” invention of claims 13-15, 21, and 24-26 of this application. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 13-15, 21, and 24-26 of the application are anticipated by claims 1-3 of US 6,863,689, it is not patentably distinct from claims 1-3 of US 6,863,689.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 13-16, 18, 20, 21, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al. (US 5,989,291; previously cited in PTO-892) in view of Stubstad et al. (US 3,867,728 A; cited in Applicants' IDS).

As seen in Figures 3b, 4, 5, and 7-9, Ralph et al. disclose an intervertebral spacer device comprising first and second plate members (e.g., 100a, 100b), each having an external plate surface (e.g., 102a, 102b) thereof, the plate members being disposed such that the external plate surfaces face in opposite directions. Ralph et al. disclose plate members 100a, 100b as convex

(see column 2, lines 61-63) and as having a porous coating (see column 3, lines 4-6; column 5, lines 57-61). Additionally, Ralph et al. teach a porous, resilient/flexible (i.e., deflectable; see column 3, lines 8-18; column 6, lines 17-21), and convex (see Figures 4 and 9) fabric/mesh (circumferential wall 120) on an external lateral portion of the intervertebral spacer device (see Figures 4, 6, and 9). Further, Ralph et al. disclose ball-shaped head 207 to be received and hold within curvate volume 233 (see columns 6 and 7).

Although Ralph et al. disclose the external plate surfaces as convex to match the contour of the opposing bone surface (see column 2, lines 61-65), and a porous coating on said external plate surfaces to provide for tissue ingrowth (see column 3, lines 4-6; column 5, lines 57-61), they did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been

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obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Ralph et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

### ***Response to Arguments***

10. Applicants' arguments filed January 30, 2006 have been fully considered but they are not persuasive. The Applicants argue that Ralph et al. '291 does not disclose the spring as "secured" to the inner surface of the plate, or the socket as "attached" to one of the plates. The Examiner respectfully disagrees. The term "secured" is generally defined as: "To capture or confine" or "Not likely to fail or give way; stable". The term "attached" is generally defined as: "Joined to or by a wall" or "To bring into an association". Based on these definitions, it should be noted that (once assembled) the spring/socket is "secured" or "attached" to one of the plates.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

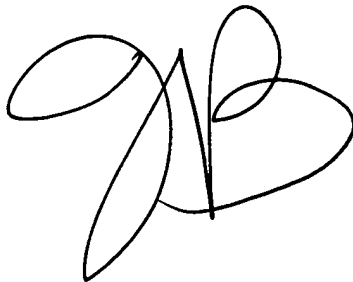
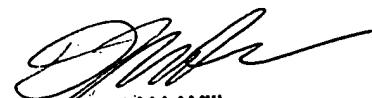
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (9:00 a.m.-6:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

February 14, 2006

A stylized, handwritten signature in black ink, consisting of several loops and a vertical stroke.A handwritten signature in black ink, appearing to be 'David H. Willse'.

**David H. Willse**  
**Primary Examiner**